Radiological Health Program

X-RAY BULLETIN

Re-issued December 1, 2004

Guidance For Mammography Facilities Regarding Patient Notification Requirements: Poor Quality Mammograms

Effective July 1, 2000, the General Assembly passed legislation authorizing the Board of Health to establish guidelines to require the licensed facilities or physicians' offices where mammography services are performed to offer to the patient, prior to departure, development of such films to ensure integrity and quality of the film. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality (*Code of Virginia* § 32.1-229-A-10).

The VDH regulates mammography machines as part of its X-ray Protection Program, independently of the federal Mammography Quality Standards Act of 1994. This means that mammography facilities are regulated by both federal and state governments.

Currently the federal mammography regulations authorizes mammography facilities to batch process mammograms where film processing is not available, such as mobile facilities, and when the film processor quality control limits are exceeded. Although there is no regulatory limit on the time after film exposure to processing, there is concern that the diagnostic information may fade due to film fogging, and facilities should process the exposed films within the time that the film manufacturer specified. This time has now been restricted to two business days as a result of the state legislation.

Facilities that can not process the mammograms during the patient's visit are obligated to inform the patient that film processing is not available during the patient's visit, and she will be informed within two business days whether a repeat visit will be necessary due to poor image quality of the films.

In the case where film processing is available during the patient's visit and the patient chooses to leave before she is informed of the need for a retake due to poor image quality, then the patient shall be informed that she will be notified within two business days whether a retake is necessary due to poor image quality. Patients may be further

advised that although a radiological technologist may inform the patient that the films appear to be "good", i.e. good image quality, the interpreting physician has the final authority for determining the need for either retakes due to poor image quality or a

suspicious finding that may warrant additional views that may require a repeat patient visit. Patients who do not need to return for a retake examination do not need to be notified; however, the facility is required to provide the patient the interpretive results of the exam with in 30 days, which is discussed in the last paragraph.

Patient notification for the need of a retake exam due to inadequate image quality may be made by telephone, fax, E-mail, or U.S. Postal Service. A notation in the patient's record shall record the date of the notification.

Consumer Complaints regarding this patient notification requirement should be in writing and directed to Leslie Foldesi, M.S., CHP, Director; Radiological Health Program; 109 Governor Street, Room 730; Richmond, VA 23219.

In addition to this state requirement, the federal mammography regulations require the mammography facility to provide to the patient the interpretive results of the mammography examination within 30 days from the examination. The results must be provided in writing either directly to the patient, or sent by U.S. Postal Service.

Published By: Virginia Department of Health, Radiological Health Program, 109 Governor St., Room 730, Richmond, VA 23219
Questions and Comments should be directed to Stan Orchel, Jr. X-Ray Program Coordinator in the Central Office at (804) 864-8170.